Select Committee on Homeland Security

U.S. House of Representatives
Washington, DC 20515

May 14, 2003

MEMORANDUM

To: Members of the Select Committee on Homeland Security

From: Select Committee on Homeland Security, Majority Staff

Subject: May 15, 2003 Hearing on "Bioshield: Countering the Bioterrorist Threat"

The Select Committee on Homeland Security will meet on Thursday, May 15, 2003, at 1:00 pm, in 2118 Rayburn House Office Building to hold a hearing on "Bioshield: Countering the Bioterrorist Threat." The hearing will examine the scope of the bioterror threat, and the technical and economic obstacles to countering the threat, in the context of the proposed Project Bioshield, which is scheduled to be marked up by the Energy and Commerce Committee on Thursday, May 15, 2003, at 10:00 am.

This hearing will put Bioshield into a broader context than previous hearings, to better understand the difficult challenge of fighting bioterrorism. The first panel will consist of scientists with specific expertise in fields related to bioterrorism. The second panel will be representatives of companies and industries that are in the business of researching and developing new drugs and treatments.

Witnesses

The following witnesses will be testifying:

Panel I

Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases

Dr. Gary Adams, Associate Dean for Research & Graduate Studies, Texas A&M

Dr. Clarence James Peters, Director for Biodefense in the Center for Biodefense and Emerging Infectious Diseases, University of Texas Medical Branch

Dr. Ronald Crystal, Professor and Chairman, Department of Genetic Medicine, Weill Medical College of Cornell University

Panel II

Eric Tolbert, Director, Response Division, Emergency Preparedness & Response Directorate/FEMA

Dr. William A. Haseltine, Chief Executive Officer, Human Genome Sciences

Alan A. Pemberton on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA)

Robert J. Sutcliffe, Director, President and Chief Executive Officer, Digital Gene Technologies, Inc.

Frank M. Rapoport, Partner, McKenna Long & Aldridge LLP

Project Bioshield Summary

Project Bioshield presently consists of three sections:

1) New NIH Authorities to Speed Research and Development on Medical Countermeasures. The bill gives the NIH new authorities to speed research and development in promising areas of medical countermeasure development. NIH's usual methods for supporting research and development on conventional diseases have been extremely effective in those areas but may not always be suited to meet the urgent demands posed by the risk of terrorism. The new authorities would apply only to support research and development on bioterrorism threat agents and include the following features:

- The Director of the National Institute of Allergy and Infectious Diseases would have increased authority and flexibility to award contracts and grants for research and development of medical countermeasures. Funding awards would remain subject to rigorous scientific peer review, but expedited peer review procedures could be used when appropriate.

- This authority would also permit more rapid hiring of technical experts, and would allow NIH to quickly procure items necessary for research.

2) Spending Authority for the Delivery of Next-Generation Medical Countermeasures. The legislation would create a reliable source of funding for long-term procurement contracts to spur development of medical countermeasures. This authority will enable the government to purchase vaccines and other therapies as soon as experts believe that they can be made safe and effective, ensuring that the private sector devotes efforts to developing the countermeasures.

- The Secretary of Homeland Security and the Secretary of Health and Human Services will collaborate in identifying critical security countermeasures by evaluating likely threats, new opportunities in biomedical research and development, and public health considerations.

- The Secretary of HHS would then be able to enter long-term contracts for the procurement of security countermeasures, with payment conditional on delivery.

3) New FDA Emergency Use Authorization for Promising Medical Countermeasures Under Development. Some of the most promising treatments for a terrorist agent may still be under formal FDA review when an attack occurs. The bill creates an emergency use authorization to permit the effective use of such treatments in an emergency, if alternative treatments are not available. This will improve access to a potentially beneficial treatment in an emergency situation, when it is most likely to save lives, even if it has not yet been proven to be suitable for routine general use or has not completed the formal process for full FDA licensure.

- The thorough process required for FDA licensure has protected the American people and provided a supply of safe and effective drugs. The administration fully supports the thorough review FDA requires before licensing a product.

- These new authorities seek to supplement the traditional FDA licensing process to ensure that we could respond in a crisis to use a medical countermeasure that experts judged to be safe and effective, but just had not completed the formal FDA process. This authority is very narrowly focused and targeted - only drugs under the direct control of the US government could be used, they could only be used after certain certifications had been made, and all civilian use would be voluntary.

- Current use of a drug prior to licensure - a so-called Investigational New Drug - has many safeguards built into it, including informed consent and extensive follow-up monitoring. These are important provisions, but in a crisis they could prevent the drug from being made available in a timely fashion to all the citizens who need it.

- The emergency use authorization would require a finding by the Secretary of Health and Human Services that the treatment in question was expected to have benefits in the emergency situation that outweighed its expected risks.

- Unlike typical medical product approvals, the emergency use authorization may be limited to particular types of medical providers, patients, and conditions of use. Thus, the authorization would allow greater flexibility in the FDA review process to meet the circumstances of specific terrorist threats.

- The emergency use authorization would remain in effect no more than one year, unless the specific terrorist threat justifies extension of the authorization and the available evidence indicates that the countermeasure is providing important expected benefits.

Contact

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